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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,592	05/04/2001	Edward T. Wei	407T-976201US	1754

22798 7590 01/27/2004

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/849,592

Applicant(s)

WEI ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 7 is/are rejected.
- 7) ☒ Claim(s) 6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the claims***

1. Response to restriction requirement filed 11/07/03 is acknowledged. Applicant elected, without traverse, Group III, claims 3-7. The claims of the elected group are amended to read on product rather than method of use thereof. Claims 1,2,9,10 are canceled. Claims pending are 3-8.

In regard to election of species requirement, applicant elected the species of claim 8. Insofar as the elected compound have been found to be neither anticipated nor rendered obvious by the prior art, the Examiner has extended his search to anisoylated derivatives of the claimed dynorphin fragment, and dynorphin fragment Ac-R-R-I-R-P-K-L-NH<sub>2</sub> encompassed by claim 3.

### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statement filed 01/30/2003 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Claim Objections***

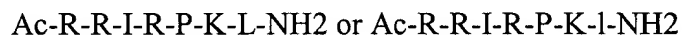
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3. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Base claim 3 is drawn to a product, whereas claim 7 is drawn to a composition comprising said product. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

***Claim Rejections - 35 USC § 102 and 103.***

4. Claims 3-5 are rejected under 35 U.S.C. 102(b,e) as clearly anticipated by Wei et al (US Patent 5,482,930; IDS, reference #06).

The reference teach dynorphin peptides, such as dynorphin fragments



(See claims 1,6,8, SEQ ID No. 3) which read on the instantly claimed peptides.

The reference further teaches peptides comprising said fragments - see, e.g., peptides SEQ ID 1,2, claims 6,8.

5. Claim 3 is rejected under 35 U.S.C. 102(a) as anticipated by Quillan and Sadee (Pharmaceutical Research, 14 (6), 713-719, 1997;IDS, reference #14).

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Quillan and Sadee teach dynorphin peptides, such as dynorphin and its 1-13, 1-11, 1-9, 1-8, 2-17, 2-13, 2-11 and 2-8 fragments. Note that the referenced dynorphin fragments read on the peptides claimed in instant claim 3, as the language "comprising" is open. The referenced peptides antagonize MC1 melanocyte receptors. See abstract and p. 714, third paragraph from the bottom. In *Xenopus* cells transfected with melanocortin receptors,  $K_d$  of inhibition of MCR-1 receptors is 87nM (see Table 1).

6. Claims 4,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quillan and Sadee as applied to claim 3 above and further in view of Wei et al. Use of pharmaceuticals in the form of their derivatives protected at N- or C- termini is well known in pharmaceutical art. See, e.g., Wei et al., col. 5, last paragraph (US Patent 5,482,930).

7. Claim 7 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Quillan and Sadee as applied to claim 3 above and further in view of Suzuki or Friedman et al. Selection of appropriate forms of delivery of a pharmaceutical is well known in the art. See, e.g., Suzuki or Friedman (US Patents 4,016,100 and

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5,514,670). Applicant's claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art.

***Conclusion.***

8. Claims 6, 8 are novel and unobvious over the prior art of record or any combination thereof. In regard to claim 8, the prior art of record does not teach or suggest dynorphin analogs wherein residues Arg<sup>6</sup> and Arg<sup>9</sup> is in D-configuration, and N-terminus is anisoylated. In regard to claim 6, prior art does not teach anisoylated derivatives of the claimed peptides.

9. Claims 6,8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 21, 2004

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written below the printed name and title.